## REMARKS

Upon entry of this paper, claims 1 and 6 have been amended, no claims have been canceled, and no claims have been added as new claims. Thus, claims 1-10 are presently pending in this application. No new matter has been added.

Summary of Invention in Pending Application

Prior to discussing the substantive rejections below, Applicants wish to provide a brief summary of some of the features relating to what they regard as their invention as claimed in the pending application. This Summary is not intended to convey all of the inventive aspects of the present invention. Instead, this Summary is intended to merely point out some of the features that have been identified as relevant to the rejections stated in the Office Action.

The present invention provides a covered stent that predictably and dependably expands to an increased diameter state at relatively low deployment pressures while concomitantly minimizing the risk of tearing of the stent covering during expansion. The stent covering is comprised of an inner cover and an outer cover that are positioned adjacent the inner surface and outer surface, respectively, of the stent structure to cover the stent. The inner cover and the outer cover can be constructed from the same or different biocompatible materials, such as, fluoropolymers like expanded polytetrafluoroethylene, having a structure of nodes interconnected by fibrils.

The inventors have determined that decreasing the radial thickness of the covering and increasing the average internodal distance (IND) of the fluoropolymer material forming the stent covering, reduces the deployment pressure necessary to expand the covered stent.

In accordance with one aspect of the present invention, the stent covering has a radial thickness of at least about 0.008" when the stent is in the reduced diameter, unexpanded state. In accordance with another aspect of the present invention, the average internodal distance of the fluoropolymer material forming either the inner cover or the outer cover is greater than 100 microns when the stent is in the reduced diameter, unexpanded state.

In one embodiment, the average IND of the fluoropolymer material forming either the inner cover or the outer cover can be at least about 110 microns. Alternatively, the average IND of the fluoropolymer material forming either the inner cover or the outer cover can be at least about 135 microns.

In accordance with a further aspect of the present invention, the stent deploys from a reduced diameter configuration to an increased diameter configuration at an average deployment pressure of less than or equal to about 10 atm. In one embodiment, the average deployment pressure of the stent is between about 4 atm and about 8 atm.

**CLAIM REJECTIONS UNDER 35 U.S.C. §103**

*Claims 1-4*

Claims 1-4 were rejected under 35 U.S.C. §103 as allegedly being unpatentable over US Patent No. 6,124,523 to Banas, et al. (Banas '523) in view of US Patent No. 6,296,661 to Davila, et al. (Davila '661). Claim 1 has been amended to more clearly identify the present invention. Applicants further distinguish the claimed invention from Banas '523 and Davila '661 according to the following remarks.

*Summary of Banas '523*

Banas '523 is directed to an encapsulated stent including a stent or structural support layer sandwiched between two biocompatible flexible layers. One embodiment has a stent cover, which includes a tubular shaped stent that is concentrically retained between two tubular shaped grafts of expanded polytetrafluoroethylene. Another embodiment has a stent graft which includes at least one stent sandwiched between the ends of two tubular shaped grafts, wherein at least a portion of the grafts are unsupported by the stent. Still another embodiment includes an articulating stented graft, which includes a plurality of stents spaced apart from one another at a predetermined distance, wherein each stent is contained between two elongated biocompatible tubular members. The graft/stent/graft assemblies all have inseparable layers.

*Summary of Davila '661*

Davila '661 is directed to a stent-graft for insertion into a target site within a vessel of a patient. The graft has a crimped state for delivery to the target site, and an expanded state for implantation therein. The graft has a self-expanding outer stent, which is a tubular member made from an elastic material. The graft further includes a tubular flexible porous graft member extending along the interior of the outer stent. The graft member has front and back ends, which are folded over and bonded to the front and back ends of the outer stent to form cuffs. In addition, the stent-graft has a self-expanding inner stent, which also is a tubular member made from an elastic material. The inner stent is disposed within the interior of the graft member such that the inner stent, the graft member and the outer stent are all abutting.

*Claims 1-4 Are Non-Obvious With Respect To Banas '523 In View Of Davila '661 Because Not All Elements Of Amended Claim 1 Are Taught Or Suggested*

Banas '523 does not teach or suggest a radially deployable stent having

"at least one of said biocompatible material of said inner cover and said biocompatible material of said outer cover has a predetermined thickness and has an average internodal distance (IND) of greater than 100 microns to reduce a deployment pressure necessary to expand the stent." *See* amended claim 1.

Davila '661 discloses an "average internodal distance greater than 115 microns." The purpose for the internodal distance as described by Davila '661 is to "allow for the migration of cells to facilitate a more stable neointima on the surface of the stent-graft implant." *See* column 8, lines 63-65. There is no mention in Davila '661 of what was determined by the inventors of the present invention that a predetermined combination of thickness and internodal distance can affect the deployment pressures, allowing lower pressures for application in smaller body vessels and other small or fragile areas.

Absent such teaching or suggestion, there can be no obviousness rejection.

*Claims 1-4 Are Non-Obvious With Respect To Banas '523 In View Of Davila '661 Because There Is No Suggestion Or Motivation For The Proposed Combination*

Banas '523 is directed to the specified and described stent and graft combination. There is no discussion in Banas '523, let alone teaching or suggestion, that applying the graft material in a predetermined thickness and internodal distance at a non-expanded state would have any effect on the deployment pressure.

Furthermore, Davila '661, as mentioned above, does not teach or suggest the modification of the graft material to effect a change in deployment pressure of the stent.

Therefore, one of ordinary skill in the art would first not be motivated by Banas '523 to look for additional references relating to deployment pressure. In addition, if Banas '523 did motivate in such a manner, one of ordinary skill in the art would not look to Davila '661 to combine with Banas '523.

Absent any suggestion or motivation to combine, there can be no obviousness rejection.

*Claim 5*

Claim 5 was rejected under 35 U.S.C. §103 as allegedly being unpatentable over Banas '523 in view of Davila '661, and in further view of US Patent No. 6,039,755 to Edwin, et al. (Edwin '755). Claim 1, from which claim 5 depends, has been amended to more clearly identify the present invention. Applicants further distinguish the claimed invention from Banas '523, Davila '661, and Edwin '755, according to the following remarks.

*Summary of Edwin '755*

Edwin '755 is directed to tubular ePTFE materials, which are capable of being radially expanded under the influence of a radially outward force applied from the lumen of the ePTFE tubular material to substantially uniformly radially deform the ePTFE material. The ePTFE material is radially expandable to a diameter 700% its unexpanded diameter under the influence of pressures less than 6 atm while retaining the structural integrity of the ePTFE microstructure. Conservation of the structural integrity of the ePTFE material is determined by conservation of the ePTFE microstructure structural integrity.

*Claim 5 Is Non-Obvious With Respect To Banas '523, Davila '661, and Edwin '755 Because Not All Elements Are Taught Or Suggested*

Claim 5 depends from claim 1. Claim 1 was amended to better point out and distinctly claim the feature of ". . . at least one of said biocompatible material of said inner cover and said biocompatible material of said outer cover has a predetermined

thickness and has an average internodal distance (IND) of greater than 100 microns to reduce a deployment pressure necessary to expand the stent and enable use of the stent." *See* claim 1.

There is no teaching in Edwin '661 of altering the internodal distance to effect a change in the deployment pressure. Therefore, the addition of Edwin '661 to Banas '523 and Davila '661 fails to meet all claimed limitations.

Absent such teaching, there can be no obviousness rejection.

*Claims 6-9*

Claims 6-9 were rejected under 35 U.S.C. §103 as allegedly being unpatentable over Banas '523 in view of Davila '661, and in further view of US Patent No. 5,993,489 to Lewis, et al. (Lewis '489). Claim 6 has been amended to more clearly identify the present invention. Applicants further distinguish the claimed invention from Banas '523, Davila '661, and Lewis '489, according to the following remarks.

*Summary of Lewis '489*

Lewis '489 is directed to a tubular intraluminal graft for repairing body conduits, made from at least one layer of porous expanded PTFE film that has a microstructure having fibrils oriented in at least two directions, which are substantially perpendicular to each other. The tubular intraluminal graft has a wall thickness of less than about 0.25 mm and may have a longitudinally or helically oriented seamline. Additional reinforcing components such as reinforcing ribs or braids may also be provided.

*Claims 6-9 Are Non-Obvious With Respect To The Cited References Because Not All Elements Of Claims 6-9 Are Taught Or Suggested*

Banas '523 and Davila '661 fail to disclose " . . . said stent covering [having] a radial thickness of at least about 0.008" and the average internodal distance (IND) of each of the inner cover and the outer cover is greater than 100 microns to reduce a deployment pressure necessary to expand the stent." *See* claim 6.

Lewis '489 is asserted to teach the radial thickness of at least 0.008 inches. However, even if Lewis '489 teaches radial thickness dimensions, the addition of Lewis '489 to Banas '523 and Davila '661 still fails to meet all the claimed characteristics of claim 6.

In view of the above, there can be no obviousness rejection of claim 6, or any claims depending therefrom. Claims 7-9 depend from claim 6 and are therefore allowable based on their dependencies in addition to their own claimed characteristics as presented in the Application.

*Claim 10*

Claim 10 was rejected under 35 U.S.C. §103 as allegedly being unpatentable over Banas '523 in view of Davila '661, and in further view of Lewis '489, and in further view of Edwin '755. Claim 6, from which claim 10 depends, has been amended to more clearly identify the present invention. Applicants further distinguish the claimed invention from Banas '523, Davila '661, Lewis '489, and Edwin '755 according to the following remarks.

*Claim 10 Is Non-Obvious With Respect To The Cited References Because Not All Elements Of Claim 10 Are Taught Or Suggested*

The combination of Banas '523 and Davila '661 does not teach or suggest " . . . said stent covering [having] a radial thickness of at least about 0.008" and the average internodal distance (IND) of each of the inner cover and the outer cover is greater than 100 microns to reduce a deployment pressure necessary to expand the stent" (*See* claim 6) as previously noted.

The addition of Lewise '489 and Edwin '755 fails to teach or suggest all the claimed characteristics of claim 6, and therefore fails to teach or suggest all the claimed characteristics of claim 10. As such, there can be no obviousness rejection.

*Postscript*

Applicants therefore respectfully submit that Banas '523, Davila '661, Lewis '489, and Edwin '755, either individually or in combination, fail to teach or suggest every characteristic of applicants' independent claims 1 and 6. Dependent claims 2-5 and 7-10 are also allowable based on their dependency on the aforementioned independent claims in addition to their own claimed characteristics. Applicants further submit that all pending claims of the present invention are not obvious with respect to, and are therefore allowable over, the cited document.

## CONCLUSION

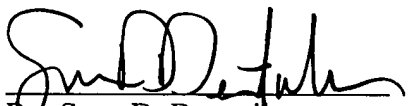
In view of the foregoing, it is respectfully submitted that this application is now in condition for allowance. Applicants courteously solicit allowance of the claims in the form of a Notice of Allowance. Should there be any outstanding issues of patentability following the entry of this response, a telephone interview is respectfully requested to resolve such issues.

Attached hereto is a marked-up version of any changes made to the Specification and/or Claims by the current Amendment. The attached page is captioned "Version With Markings To Show Changes Made".

Please charge any shortage or credit any overpayment of fees to our Deposit Account No. 12-0080. In the event that a petition for an extension of time is required to be submitted herewith, and the requisite petition does not accompany this response, the undersigned hereby petitions under 37 C.F.R. §1.136(a) for an extension of time for as many months as are required to render this submission timely. Any fee due is authorized to be charged to the aforementioned Deposit Account. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

LAHIVE & COCKFIELD, LLP



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## VERSION WITH MARKINGS TO SHOW CHANGES MADE

*IN THE SPECIFICATION*

The Specification has been amended as follows:

The paragraph beginning at page 4, line 6, with the following re-written paragraph:

—The stent structure 12 can be a balloon expandable slotted stent such as described in U.S. Patent No. 4,739,762 to Palmaz, incorporated herein by reference, as illustrated in FIGURES 1 and 2. Alternatively, the stents described in commonly-assigned U.S. Patent Application No. ~~(Attorney Docket No. ATA-268)~~ 09/628,096, filed concurrently herewith, can be employed. Other types of balloon expandable stents that can be used in the present invention include, for example, WITKOR stents described in U.S. Patent No. 4,969,458, STRECKER stents described in U.S. Patent No. 5,405,378, or PALMAZ-SCHATZ stents described in U.S. Patent No. 5,195,984. Alternatively, self-expanding stents, such as, for example, Nitinol stents, stents described in commonly-owned U.S. Patent Application No. 09/237,197, filed January 25, 1999, GIANTURCO stents described in U.S. Patent No. 4,580,568 or WALLSTENTs described in U.S. Patent No. 4,544,771, can be used in conjunction with the present invention. One skilled in the art will appreciate that the present invention is not limited to any particular stent design, and that any radially expandable stent can be employed in the present invention. All of the above-referenced patents and patent applications are incorporated herein by reference.—

The paragraph beginning at page 11, line 11, with the following re-written paragraph:

—Animal studies were conducted in which eight covered stents were deployed in the arteries of two male pigs to observe the cellular response to the stents. The stents employed were balloon expandable stents of the type described in commonly-assigned U.S. Patent Application No. ~~(Attorney Docket No. ATA-268)~~ 09/628,096, filed concurrently herewith. The stents were covered in accordance with the method described above. A single ePTFE tube was utilized to provide the inner cover and the outer cover. The stents had expanded diameters of 6 - 8 mm. The ePTFE used to cover each stent had a wall thickness of 0.01 in. and an average IND of 139 microns in the unexpanded configuration.—

*IN THE CLAIMS*

Claims 1 and 6 have been amended as follows:

1. (Amended) A radially deployable stent comprising:

a stent structure having an inner surface and an outer surface, and

a stent covering comprising

an inner cover of biocompatible material positioned adjacent said inner surface of said stent structure, and

an outer cover of biocompatible material positioned adjacent said outer surface of said stent structure,

wherein at least one of said biocompatible material of said inner cover and said biocompatible material of said outer cover has a predetermined thickness and has an average internodal distance (IND) of greater than 100 microns to reduce a deployment pressure necessary to expand the stent.

6. (Amended) A radially deployable stent comprising:

a stent structure having an inner surface and an outer surface, and

a stent covering comprising

an inner cover of biocompatible material positioned adjacent said inner surface of said stent structure, and

an outer cover of biocompatible material positioned adjacent said outer surface of said stent structure,

wherein said stent covering has a radial thickness of at least about 0.008" and the average internodal distance (IND) of each of the inner cover and the outer cover is greater than 100 microns to reduce a deployment pressure necessary to expand the stent.